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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/577,694	05/22/2000	Anne Sorensen	Novo-029	3706

7590

04/08/2003

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EXAMINER

HON, SOW FUN

ART UNIT

PAPER NUMBER

1772

DATE MAILED: 04/08/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

AS9

Office Action Summary	Application No.	Applicant(s)	
	09/577,694	SORENSEN ET AL.	
	Examiner	Art Unit	
	Sow-Fun Hon	1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-42 is/are pending in the application.
- 4a) Of the above claim(s) 21,22,41 and 42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

1. Newly submitted claims 41-42 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Applicant elected the product claims for prosecution in Paper # 5 (filed 07/02/02). The process claims 21-22 were restricted from the product claims in Paper # 4 (mailed 03/26/02) since the product can be made by forming a suspension of the rubber particles in a solution of the thermoplastic polymer, evaporating the solvent and molding the blend in a cast mold, which is a different process.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 41-42 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Withdrawn Rejections

2. The 35 U.S.C. 112, 2nd paragraph and 102(b) rejections and objections of claims 1-20 in Paper # 6 (mailed 09/26/02) have been withdrawn due to cancellation of said claims in Paper # 8 (filed 01/30/03).

New Rejections

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 23-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Kasai et al. (US 4,444,330).

Kasai et al. teaches a stopper comprising an injection-mouldable blend of 30 to 90 weight % partially crosslinked butyl based rubber and up to 30 weight % thermoplastic polyolefin. The polyolefin is taught to be polypropylene or polyethylene. The butyl based rubber is a halogenated one (column 1, lines 35-65 and column 3, lines 5-15) such as a bromobutyl rubber. Kasai et al. teaches that the butyl rubber alone is subject to permanent set and cannot provide a stopper for hermetically sealing a medical container (column 2, lines 15-65) thus teaching that a stopper made from a combination of the butyl rubber and another component provides for a hermetically sealed container resulting in a reduced leakage of substances compared to a stopper made from butyl rubber alone. Because Kasai et al. teaches that the bromobutyl rubber is at least partially crosslinked, is blended with up to 30 % polypropylene or polyethylene, and that the stopper is injection molded, in the absence of clear comparative data, it is the examiner's position that the resultant stopper has a hardness of 40-80 Shore A.

Kasai et al. teaches a medical container with non-flexible walls (rigid) (column 1, lines 5-15). The figures show that the stopper has a circular cross-section, and that the container comprises a distal and a proximal end, and at least one wall defining an interior space for storing liquid medicament (figures and column 5, lines 40-60).

Even though product by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does

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not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (*Fed. Cir.* 1985). In the instant case, the stopper is in the container, and any way of pushing the stopper in, whether the applied force to the stopper is through a rod or palm of a hand results in a stoppered container.

Response to Arguments

5. Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection due to cancellation of said claims in Paper # 8 (filed 01/03/03).

6. However, in order to advance prosecution, the pertinent arguments presented by Applicant with respect to Kasai et al. is addressed below.

7. Applicant argues that since the stopper claimed in the present application has in claim 1 a composition which is 70-90 % by weight butyl rubber and 30-10 % by weight of a thermoplastic while the composition of Kasai et al. contains 30 to 90 % by weight butyl rubber and 70 to 10 % by weight of a thermoplastic, the presently claimed composition is clearly different and patentably distinct from that of Kasai.

Applicant is respectfully reminded that:

a. Kasai et al. teaches that moldability of the stopper is improved if the thermoplastic is added in an amount up to 30 % ('330, column 1, lines 55-65) and that the hermetic sealability of the stopper is improved if the amount of the thermoplastic added

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to the butyl rubber falls within the range of 70 to 10 %, wherein if the amount of thermoplastic is less than 10 % the effects of the thermoplastic is not satisfactory ('330, column 2, lines 15-45). In short, Kasai et al. teaches that the upper limit for the thermoplastic amount is 30 % for improved moldability of the stopper and that the lower limit for the thermoplastic is 10 % for improved hermetic sealability of the stopper.

b. The criticality of the particular range must be demonstrated, generally by showing that the claimed range achieves unexpected results relative to the prior art range." In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP § 716.02 - § 716.02(g) for a discussion of criticality and unexpected results.

8. Applicant argues that there are a number of factors influencing the hardness of a given material blend such as the amount and type of additives and/or fillers such that Kasai et al. does not inherently teach a stopper having a shore hardness of 40-80.

Applicant is respectfully apprised that commercial butyl rubber has a Shore A hardness of 40 to 90 as shown by the teaching document (Baxter Rubber Company) so that there is reason to anticipate a shore hardness of 40 to 80 for the stopper when a thermoplastic is added in a small amount of less than 30 %.

9. Applicant argues that Kasai et al. does not teach that the stopper material has barrier properties against water and m-cresol and does not mention the problem of substances leaking from the solution over time.

Applicant is respectfully apprised:

a. That the properties mentioned are not present in the claims, and that an amendment to the claims reflecting said properties would then be rejected with the

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position taken that the properties are inherent in the composition of Kasai et al. since the materials are the same, unless clear comparative data were presented to demonstrate otherwise;

b. Kasai et al. does teach that leakage of the contents (blood) is prevented ('330, column 6, lines 10-15).

10. Applicant argues that the present application uses a harder composition for the stopper than butyl based rubber alone, yet preserving the leakage and barrier properties of the butyl based rubber alone so that a skilled person looking to solve the problem of reducing leakage and improving barrier properties would not look to Kasai et al. for the solution.

Applicant is respectfully reminded that Kasai et al. does teach that butyl rubber alone is subject to permanent set and cannot provide a stopper for hermetically sealing a medical container, thus inferring that a stopper made from a combination of the butyl rubber and another component provides for a hermetically sealed container resulting in a reduced leakage of substances compared to a stopper made from butyl rubber alone. Kasai also teaches that the combination of materials has satisfactory barrier properties ('330, column 2, lines 15-65). Hence regardless of whether or not it is obvious to use a harder stopper material for sealability, the invention of Kasai et al. is directed toward the hermetic sealing of a medical container and the reduction of leakage of its contents, and teaches the claimed composition which comprises the thermoplastic added to the butyl rubber.

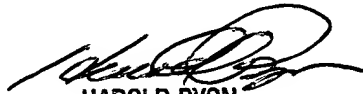
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Any inquiry concerning this communication should be directed to Sow-Fun Hon whose telephone number is (703)308-3265. The examiner can normally be reached Monday to Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on (703)308-4251. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9311.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0661.

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Sow-Fun Hon
03/31/03


HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772 4/3/03